K061249

JUN - 2 2006

Special 510(k) Summary

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

According to the requirements of 21 CFR §807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter's Name and Address:

Abbott Laboratories
Diagnostics Division
100 Abbott Park Road
Abbott Park, Illinois 60064-3500
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Contact: Kenton.Smith@abbott.com

Date Prepared: May 2006

Device Proprietary Name: AxSYM® Digoxin III
Device Common Name: Digoxin
Classification Number: Toxicology, 21 CFR §862.3320

Predicate Device:

AxSYM Digoxin II
510(k) Number: K953718

Device Description:

The AxSYM Digoxin III Reagent Pack is composed of the following reagent components:

- Digoxin: Alkaline Phosphatase Conjugate
- Anti-digoxin (Rabbit) Coated Microparticles
- MEIA Buffer
- Digoxin III Probe Wash Solution

The AxSYM Digoxin III Calibrators contain six bottles of accurately measured amounts of digoxin prepared in recalcified human plasma, nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HCV, and anti-HIV-1/HIV-2.

The AxSYM Digoxin III Controls contain three bottles of accurately measured amounts of digoxin prepared in recalcified human plasma, nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HCV, and anti-HIV-1/HIV-2.

Intended Use:

The AxSYM Digoxin III assay is a microparticle enzyme immunoassay (MEIA) for the quantitative measurement of digoxin, a cardiovascular drug, in serum or plasma. The measurements obtained are used in the treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

Comparison to Predicate Device:

Attribute	AxSYM Digoxin II Predicate Device	AxSYM Digoxin III Modified Device
Analyte Measured	Digoxin	Same
Assay Principle	MEIA technology, competitive format	Same
Instrumentation	Abbott AxSYM Analyzer	Same
Sample Type	Serum or plasma	Same
Sample Volume	150 µL (Routine) 131 µL (STAT)	194 µL (Routine and STAT)
Sample Pretreatment	No	No
Assay Type	Quantitative	Same
Dynamic Range	0.0 to 4.0 ng/mL (0.00 to 5.12 nmol/L)	Same
Calibrator Values	0.0, 0.5, 1.0, 2.0, 3.0, and 4.0 ng/mL (0.00, 0.64, 1.28, 2.56, 3.84, and 5.12 nmol/L)	Same
Control Values	0.9, 1.9, and 3.2 ng/mL (1.15, 2.43, and 4.10 nmol/L)	Same
Sensitivity	0.3 ng/mL (0.38 nmol/L)	Same
Immunoassay Format	2-step	1-step
Saponin (%) in Conjugate Diluent	0.13	0.3
Antibody	Rabbit Polyclonal	Same
Conjugate	Digoxin: Alkaline Phosphatase	Same

Bilirubin Interference at 20 mg/dL	Less than 10%	Less than 20%
Drug Compound Interference (Aldosterone inhibitors and other steroids)	–33% to –3%	–2% to 2%
Probe Wash Solution Ingredients	2 M sodium chloride 0.1% sodium azide	2 M sodium chloride 0.1% sodium azide 0.5% Triton X-100 0.05% antifoam
Medium Control Range (Target: 1.9 ng/mL)	1.50 to 2.30 ng/mL	1.43 to 2.38 ng/mL
High Control Range (Target: 3.2 ng/mL)	2.60 to 3.80 ng/mL	2.50 to 3.90 ng/mL

Conclusion: Results of laboratory testing demonstrate that the performance of the Abbott AxSYM Digoxin III assay is acceptable and comparable to the performance of the predicate device, when used according to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Kenton L. Smith
Senior Regulatory Affairs Specialist
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100 Abbott Park Road
Abbott Park, Illinois 60064-3500

JUN - 2 2006

Re: k061249
Trade/Device Name: AxSYM® Digoxin III
Regulation Number: 21 CFR§ 862.3320
Regulation Name: Digoxin test system
Regulatory Class: Class II
Product Code: KXT, JIT, JJX
Dated: May 3, 2006
Received: May 4, 2006

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061249

Device Name: AxSYM® Digoxin III

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061249